HEALTHCARE SERVICE AND SUPPLY
510(k) SUMMARY
PVA (Pneumatic Venous Augmentation)/ALP® (Alternating Leg Pressure®) Foot Garment Pump System

I. NAME OF SUBMITTER

Healthcare Service and Supply
P.O. Box 1788
Tustin, CA 92681
Phone: (714) 669-8803

Contact person: Rick Roeder
Establishment Registration Number: 2030561

II. DEVICE NAME AND CLASSIFICATION

Proprietary Name:	Healthcare Service and Supply ALP® Alternating Leg Pressure Pump and Garments for the Limb
Common or Usual Name:	Compression Sleeve, Limb
Classification:	Class II; CV JOW 870.5800

III. PREDICATE DEVICES

The Healthcare Service and Supply ALP® Pump and Limb Garments are substantially equivalent to devices in commercial distribution by the following companies:

- Healthcare Service and Supply ALP® 501 Pump System, Tustin, CA 92681; K955853, K964188
- Progressive Medical Technology, Inc., Talley 300 Sequential Multicom Compression System, 815 Terminal Road, Lansing, MI 48906; K915092
- Kendall Healthcare Products A-V Impulse System®, with Impad® Rigid Sole Foot Cover, Mansfield, MA; K953648, K951683

IV. DESCRIPTION

The ALP® consists of an electrically-operated pump and controller with inflatable limb garments (or limb compression sleeves). The ALP® 501 pump, when used in connection with the Limb Garments, supplies a measured, intermittent, fully adjustable pressure into the limb garments worn by the patient. The pump and controller rhythmically squeeze the limb in a simulation of normal muscle contraction, by pumping air into the air bladder garments wrapped around the leg.

The ALP® Pump and Limb Garments are provided non-sterile.

V. INTENDED USE

The intended use of this device, as well as the predicate devices, is to provide for external limb compression in order to artificially imitate the pumping action of the leg muscles. This provides the muscle contraction required by the venous return system, thereby helping to prevent venous stasis and subsequent thrombosis and embolism. The cyclic and alternating inflation and deflation of the garments closely simulates the normal healthy pumping action of the limb muscles to stimulate deep venous blood flow and the reactivation or increase in the body's fibrinolytic system.

This submission is intended for a change in the pump labeling to include the use of the pump at pressure levels of 40 to 120 mm Hg.

VI. TECHNOLOGICAL CHARACTERISTICS

The ALP® Pump and Limb Garments has the same technological characteristics as its predicate devices. The materials used in the limb garments are the same and the operation of the pumps and the garments is also the same. The use of the ALP® pump at the increased pressure level is equivalent to the use of predicate device pumps at the same pressure levels.

No new technology is being introduced in the design of the PVA/ALP® Foot Garment Pump System. Testing performed by Healthcare Service and Supply has shown that the pump is equivalent in performance to the use of the ALP® pump at the previous operating ranges and is equivalent to the use of predicate device pumps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2000

Mr. Rick Roeder
President
Healthcare Service and Supply
P.O. Box 1788
Tustin, CA 92681

Re: K000303
Trade Name: Healthcare Service and Supply PVA (Pneumatic Venous Augmentation)/ ALP® (Alternating Leg Pressure®) Foot Garment Pump System
Regulatory Class: II
Product Code: JOW
Dated: May 3, 2000
Received: May 3, 2000

Dear Mr. Roeder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion , or advertising, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Brian E Haberman for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Healthcare Service and Supply

510(k) Number (if known): N/A*

Device Name: **PVA (Pneumatic Venous Augmentation)/ ALP® (Alternating Leg Pressure®) Foot Garment Pump System**

Indications For Use:

The Healthcare Service and Supply **PVA (Pneumatic Venous Augmentation)/ALP® (Alternating Leg Pressure®) Foot Garment Pump System** is recommended for use in patients for whom external compression therapy using the ALTERNATING LEG PRESSURE® SYSTEM (ALP®) is indicated to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombosis formation, to reduce swelling, pain and compartment pressures after tissue trauma, and to enhance arterial blood flow.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number k000303

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter _____
Per 21 CFR 801.109